

REMARKS

Claims 1-127 are pending in the present application with claims 4, 5, and 10-127 having been withdrawn from further consideration. By the present communication, no claims have been added or canceled, and claims 1 and 2 have been amended to define Applicants' invention with greater particularity. Support for the amendments may be found throughout the specification and claims as filed. Accordingly, upon entry of the present amendment, claims 1-3 and 6-9 will be under consideration.

Rejections under 35 U.S.C. §101 and 35 U.S.C. §112, First Paragraph

Applicants respectfully traverse the rejection of claims 1-3 and 6-9 under 35 U.S.C. §101, as allegedly lacking patentable utility. Specifically, the Office Action alleges that since the polynucleotides claimed are sequences derived from a conceptual model of what should encompass homologs of cysteine:glucosaminyl inositol ligase and for the most part have not been identified in any biological systems, credible utility appears to be lacking. Without acquiescing to the reasoning offered by the Office, and in order to expedite prosecution of the instant application, Applicants have amended claims 1 and 2 to remove the terms "derivative thereof" and "conservative variations thereof." In addition, claim 2 has been amended to recite that the amino acid sequence has 54% or more sequence identity to SEQ ID NO: 2 or 4. Support for the amended claim language may be found, among others, at paragraph [0059] of the specification as filed. Applicants respectfully direct the Examiner's attention to Examples 1-5, 7, 8, 12, and 13 of the specification as filed, which disclose the identification of cysteine:glucosaminyl inositol ligases and homologs thereof. In particular, Applicants respectfully direct the Examiner's attention to Figure 4, which shows an alignment of the amino acid sequences of orthologs of SEQ ID NO: 2. As indicated in paragraph [0059] of the specification as filed,

[a] BLAST search with the *M. tuberculosis* MshC sequence on GenBank revealed additional homologs in *Corynebacterium striatum* (Accession # AAG03366) (SEQ ID NO: 5) and *Streptomyces coelicolor* (Accession # CAC36366) (SEQ ID NO: 6). The sequences for these MshC proteins are included in Figure 4 and have 54-58% identity to the *M. tuberculosis* and *M. smegmatis* sequences.

As such, Applicants respectfully submit that one of skill in the art, in view of the specification as filed and either SEQ ID NO: 2 or 4, would understand how to obtain sequences having 54% or more sequence identity to SEQ ID NO: 2 or 4 that have cysteine:glucosaminyl inositol ligase activity in the presence of a cysteine and a glucosaminyl inositol for use in the methods of the invention. In addition, one of skill in the art, in view of Examples 2 and 12 of the specification as filed, would understand how to perform the ligase assay used to obtain such sequences. Accordingly, the claimed subject matter has a credible, substantial, patentable utility, and withdrawal of the rejection is respectfully requested.

Applicants respectfully traverse the rejection of claims 1-3 and 6-9 under 35 U.S.C. §112, first paragraph, as allegedly lacking patentable utility. Specifically, the Office Action alleges that since the claimed invention is not supported by either a credible, substantial or asserted utility, one of skill in the art would not know how to use the claimed invention. The arguments presented above apply equally and are incorporated here. Applicants respectfully submit that one of skill in the art, in view of the specification as filed, would understand how to obtain sequences having 54% or more sequence identity to SEQ ID NO: 2 or 4 that have cysteine:glucosaminyl inositol ligase activity in the presence of a cysteine and a glucosaminyl inositol. In addition, Examples 2 and 12 specifically disclose assays relevant to inhibition of MshC ligase activity. Accordingly, Applicants respectfully request withdrawal of the rejection.

Rejections under 35 U.S.C. §112, Second Paragraph

Applicants respectfully traverse the rejection of claims 1-3 and 6-9 under 35 U.S.C. 112, second paragraph, as allegedly failing to particularly point out and distinctly claim the subject matter that applicant regards as the invention. Specifically, the Office alleges that it is unclear what the expression “derivative thereof” is referring to. Without acquiescing to the reasoning offered by the Office, and in order to expedite prosecution of the instant application, Applicants have amended claim 1 to remove the expression “derivative thereof,” rendering the rejection moot. Accordingly, Applicants respectfully request withdrawal of the rejection.

Rejections under 35 U.S.C. §112, First Paragraph

Applicants respectfully traverse the rejection of claims 1-3 and 6-9 under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. Specifically, the Office alleges that the specification, claims and the art do not adequately describe the distinguishing features or attributes concisely shared by the members of the genus comprising any polypeptide sharing at least 35% sequence identity with SEQ ID NO: 2 or 4, or conservative variations thereof. According to the Office Action, the genus of homologs claimed encompasses a vast array of structures. M.P.E.P. §2163 states that “there is no *per se* rule that an adequate written description of an invention that involves a biological macromolecule must contain a recitation of known structure.” (citing *Falkner v. Inglis*, 448 F.3d 1357, 1366, 79 USPQ2d 1001, 1007 (Fed. Cir. 2006)). Further, “[a]n applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.” (citing *Enzo Biochem.*, 323 F.3d at 964, 63 USPQ2d at 1613).

Without acquiescing to the reasoning offered by the Office, and in order to expedite prosecution of the instant application, Applicants have amended claims 1 and 2 to remove the terms “derivative thereof” and “conservative variations thereof.” In addition, claim 2 has been amended to recite that the amino acid sequence has 54% or more sequence identity to SEQ ID NO: 2 or 4. As discussed above, Applicants respectfully submit that one of skill in the art, in view of the specification as filed and either SEQ ID NO: 2 or 4, would understand how to obtain sequences having 54% or more sequence identity to SEQ ID NO: 2 or 4 that have cysteine:glucosaminyl inositol ligase activity in the presence of a cysteine and a glucosaminyl inositol for use in the methods of the invention. Accordingly, Applicants respectfully request withdrawal of the rejection

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Conclusion

In view of the amendments and above remarks, it is submitted that the claims are in condition for allowance, and a notice to that effect is respectfully requested. The Examiner is invited to contact Applicant's undersigned representative if there are any questions relating to this application.

No fee is believed to be due in connection with the filing of this paper. However, the Commissioner is hereby authorized to charge any fees that may be required by this paper, or credit any overpayment to Deposit Account 07-1896 referencing the above-identified attorney docket number.

Respectfully submitted,



Antony M. Novom, J.D.
Registration No. 45,517
Telephone: (858) 638-6641
Facsimile: (858) 677-1465

DLA Piper US LLP
4365 Executive Drive, Suite 1100
San Diego, California 92121-2133
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